MAR 1 0 2014

Section 5: 510(k) Summary

510(k)# K121123

General Information

Classification	Class II
Trade Name	Biofusionary Bebe™ System
Product Code:	IMJ
Regulation Number:	21 CFR 890.5290
Common Name:	Shortwave Diathermy
Submitter	Rocky Mountain Biosystems, Inc. 3930 Youngfield Street Wheat Ridge, CO 80033 Tel: (303)277-1140 Fax: (303)277-1150
Contact	Kevin Marchitto, Ph.D.
Date:	March 5, 2014

Intended Use

The Biofusionary Bebe System is indicated to be used to generate deep heat within body tissues for treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

Predicate Device(s)

Chattanooga Group-Intelect SWD 100, K083433

Device Description

The Biofusionary Bebe is used for diathermic heating of tissue. The Biofusionary Bebe hand piece tip is comprised of a coil shaped antenna which directs the flow of current parallel to the tissue surface, without contacting the tissue surface, thereby directing the magnetic component of the electromagnetic energy into tissue to result in the formation of eddy currents in tissue. These eddy currents encounter resistance, leading to localized heating.

Materials

The Biofusionary Bebe is comprised of the following main components:
Main console containing the major electrical components including:

- Radiofrequency (RF) generator
- Control module

- Footswitch
- Recirculating chiller
- Isolation transformer
- Connection ports for hand piece, footswitch and power cord

Hand piece incorporating:

- Treatment tip
- Umbilical connection to main console.

All materials used in the manufacture of the Biofusionary Bebe are suitable for this use and have been used in numerous, previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification. The results showed the system met specification.

Additionally, the product passed numerous bench studies and animal studies where heating capabilities were evaluated; these include bench top studies on tissue phantoms and samples of *ex vivo* porcine skin tissue, *in vivo* studies on rats and two clinical studies completed to further determine feasibility and safety and effectiveness.

In heating characterization studies, phantoms were used to mimic treatment sites. A heating treatment protocol described in the User Manual resulted in reaching a therapeutic level of 40 °C in approximately 5 minutes at the surface. A temperature of 40 °C was reached within 5 to 10 minutes at 1cm and within 8 to 13 minutes at 2 cm. The surface of the phantom did not exceed 45 °C for the duration of the study.

A usability study was conducted in which naive users were first instructed to review the User Manual and protocols for use of the device, followed by actual use of the device in a mock setting. The users were questioned and observed. The results of the study indicated that the instructions were adequate. The users understood the instructions and could apply the device according to the instructions.

Occupational testing for safe levels of exposure to electromagnetic energy was performed in accordance with the safety standard IEEE 95.1-2005.

The Biofusionary Bebe complies with the following performance standards:

#	Standards #	Standards Organization	Standards Title	Version	date
1	13485	ISO	Medical Devices - Quality Management Systems - Requirements for regulatory purposes	2003	1/16/2012
2	14971	ISO	Medical Devices - Risk Management - Part 1: Application of risk analysis	2007	1/16/2012
3	10993-1	ISO	Biological Evaluation of Medical Devices - Part 1 - Evaluation and Testing	2009	1/16/2012
4	EN 60601-1 (1990) +A1 (1993) +A2 (1995) +A12 (1993) +A13 (1996)	IEC	Medical electrical equipment - General requirements for safety	60601-1 (1990) +A1 (1993) +A2 (1995) +A12 (1993)	1/16/2012

	+Corrigenda (July 1994)			+A13 (1996) +Corrigenda (July 1994)	
5	EN 60601-2-3	IEC	*Medical electrical equipment - Part 2: Particular requirements for the safety of short-wave therapy equipment	1993	1/16/2012
6	EN 55011 (2009) +A1 (2010)	IEC	Industrial, scientific and medical equipment, Radio-frequency disturbance characteristics. Limits and methods of measurement	EN 55011 (2009) +A1 (2010)	1/16/2012
7	IEC 60601-1-2	IEC	Essential Performance, Risk Analysis and Immunity Testing	3rd ed. (2007-03)	1/16/2012
8	CISPR 16-1	CISPR	Specification for radio disturbance and immunity measurement apparatus and methods - Part 1: Radio disturbance and immunity measuring apparatus	Ed. 2.1 (2002-10)	1/16/2012
9	CISPR 11	CISPR	Industrial, scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement.	Ed. 5.0 (2009-05)	1/16/2012
10	CISPR 16-2	CISPR	Specification for radio disturbance and immunity measurement apparatus and methods - Part 2: Methods of measurement of disturbances and immunity	Ed/ 2.0 (2003-07)	1/16/2012
11	CISPR 16-3	CISPR	Specification for radio disturbance and immunity measurement apparatus and methods - Part 3: Reports and recommendations of CISPR	Ed. 1.1 (2002-08)	1/16/2012
12	CISPR 16-4	CISPR	Part 4-1: Uncertainties, statistics and limit modeling — Uncertainties in standardized EMC tests	Ed. 1.0 (2002-05)	1/16/2012
13	EN 61000-3-3	IEC	Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection.	2008	1/16/2012
14	EN 61000-3-2 +A1 (2009) + A2 (2009)	IEC	Electromagnetic compatibility (EMC) - Part 3-2 - Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)	2006 +A1 (2009) + A2 (2009)	1/16/2012
15	EN 60601-1-4	IEC	Collateral Standard – Programmable electronic systems	2000	1/16/2012
16	IEEE C95.1	IEEE	Safety Levels with Respect to Human Exposure to Radiofrequency Electromagnetic Fields, 3 kHz to 300 GHz.	2005	1/16/2012

* The 60601-2-3 standard is not recognized by the FDA

Summary of Substantial Equivalence

The Rocky Mountain Biosystems, Inc, Biofusionary Bebe™ System is equivalent to the predicate product. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent. The results of heating studies also support the substantial equivalence of the Biofusionary Bebe with the predicate device.

Technological Characteristics

The predicate product, the Chatanooga Intelect, is supplied with two different electrodes: the Monode (Drum) Electrode is an induction coil for treatment of mid-sized areas. The Diplode is a capacitive coupled set of electrodes for treatment of large areas and for treatment of suitable body parts that can be warmed from three sides at the same time. The device may be operated in pulsed or continuous mode.

The drum electrode, an induction coil, has a 14 cm diameter. It is fixed in size and attached to a boom that allows it to be positioned at a single location on the patient. The fixed nature of the electrode allows the operator to provide hands-free treatment of a 14 cm diameter area of the skin.

The operation of the Biofusionary Bebe device is most similar to the use of the Intelect Monode Electrode used in continuous mode

The Biofusionary Bebe device has a hand piece with 3 cm diameter tip. The device operates in continuous mode at 170W. The device allows the operator to treat a 12 cm diameter area by choosing timer settings and protocols. Hands-free operation is not possible.

Power delivery

Both devices operate at 27.1 MHz.

The Intelect allows for operation in a pulsed mode (200 W) with a variable duty cycle, or a continuous mode (100 W) with variable power settings. The Biofusionary Bebe operates in a fixed continuous mode at 170W.

The operation of the Biofusionary Bebe device is most similar to the use of the Intelect Monode used in continuous mode operation.

Applicator

The Intelect is supplied with a drum electrode, the induction coil, which has a 14 cm diameter. It is fixed in size and attached to a boom that allows it to be positioned at a single location on the patient. The fixed nature of the electrode allows the operator to provide hands-free treatment of a 14 cm diameter area of the skin.

The Biofusionary Bebe device has a hand piece with 3 cm diameter tip. The device allows the operator to treat a 12 cm diameter area by choosing timer settings and protocols. Hands-free operation is not possible.

Heating Capabilities

Two different electrode configurations are available for the Intelect. The Monode (Drum) Electrode is an induction coil for treatment of mid-sized areas. The Diplode is a capacitive coupled set of electrodes for treatment of large areas and for treatment of suitable body parts that can be warmed from three sides at the same time.

The devices manage deep or shallow heating capabilities in similar manner:

Both devices heat to therapeutic temperatures for a minimum of 1 minute, and the maximum recommended treatment time is 30 minutes. Both devices provide therapeutic heating for the duration of the treatment cycle, once the therapeutic temperature is reached.

Both devices provide instructions and warnings for variable depth heating.

The Intelect User Manual directs: "The Electrode-Skin Distance (ESD) must be small for surface warming and large for depth warming. A larger Electrode-Skin Distance (ESD) is necessary for patients with a thick layer of subcutaneous fat in order to achieve the necessary warming of deep-lying tissue."

The Biofusionary Bebe provides protocols in the User Manual that aid the operator in applying heat to the tissues appropriately.

Safety Precautions:

Patient treatment criteria and warnings are provided in the User Manuals of both the Intelect and Biofusionary Bebe to assure safe and effective treatment:

The Intelect manual recommends four different dosage levels for operation using patient feedback to accommodate patients with different pain sensation levels, the lowest level being used for those who cannot sense pain.

The Biofusionary Bebe requires user feedback to determine the appropriate conditions of treatment. The User Manual provides warnings and protocols to address patients with little or no sensation of pain.

Both devices rely on patient feedback to avoid the risk of excessive warming, and both devices provide similar warnings, cautions and contraindications in their User Manuals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – W066-G609
Silver Spring, MD 20993-0002

March 10, 2014

Rocky Mountain Biosystems, Inc.
c/o Kevin Marchitto
President
3930 Youngfield Street
Wheat Ridge, CO 80033

Re: K121123
Trade Name: Biofusionary Bebe™ System
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave Diathermy
Regulatory Class: Class II
Product Code: IMJ
Dated: January 6, 2014
Received: January 8, 2014

Dear Mr. Marchitto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K121123

Device Name
Biofusionary Bebe System

Indications for Use *(Describe)*
The Biofusionary Bebe System is indicated to be used to generate deep heat within body tissues for the treatment of medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S

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